THE OHIO STATE UNIVERSITY

TIP SHEET:
EXEMPT CATEGORY 3

In the revised Common Rule (Final Rule), the former exempt category 3 (interviews with publicly elected officials) has been replaced with a new category for "benign behavioral interventions." Research that previously would have qualified for the former exempt category 3 can now be approved under exempt category 2.

Exempt category 3

Research involving benign behavioral interventions (brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact, and the investigator has no reason to think that the participants will find the interventions offensive or embarrassing) in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(a) The information obtained is recorded without direct or indirect identifiers;

(b) Disclosure outside of the research would not reasonably place the subjects at risk of harm (e.g., legal, financial, reputational, employability); or

(c) The information obtained is recorded with either direct or indirect identifiers and there are adequate protections in place for protecting privacy and maintaining confidentiality. *(Requires limited IRB review.)*

What methods of data collection are acceptable under exempt category 3?

Methods of data collection are limited to verbal or written responses from subjects (e.g., surveys or interviews, test responses, or data entry), observation, and audiovisual recording. Data cannot be collected via physical procedures, such as blood pressure monitoring, EEG, activity trackers (e.g., Fitbit), eye trackers, and blood draws under this exempt category.

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My study involves deception. Is it eligible for exemption under category 3?

Yes—provided it meets certain conditions. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject is informed in advance that he or she will be unaware of or misled regarding the nature or purposes of the research. Participants must be informed that the true purpose of the research will be withheld, rather than that the possibility that deception may be used. This is called prospective agreement.

For studies using deception via prospective agreement, the following statement must be included in consent materials:

> "You will not be fully informed about the nature of the study before your participation."

If a debriefing script or document will be used, also add the following:

> "After the study, you will receive more information and have the option to withdraw from the study if you so choose."

What is limited IRB review?

The third criterion under exempt category 3 allows research that collects sensitive identifiable data, but requires "Limited IRB Review" to ensure that adequate protections are in place to protect subject privacy and the confidentiality of data. This means that the IRB must review and approve procedures for data management and security when sensitive information is collected with either direct identifiers or indirect identifiers, such as a code that can link back to the participant, or data elements that could be combined to readily re-identify a subject.

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Exempt category	Study example	Exempt?	Explanation
3	Subjects play a violent video game and complete a written test. The investigator describes the study procedures and intervention, and subjects (who play video games regularly) prospectively agree to participate.	Yes	**Benign** behavioral intervention (subjects are unlikely to be offended); collection of **non-sensitive** information via **written** responses; prospective **agreement**.
3	Subjects prospectively agree to memorize and recall a list of words while being distracted; responses are audio recorded. Subjects are told they will be unaware or misled regarding the nature or purpose of the study. The investigator conceals details of the distraction.	Yes*	**Benign** behavioral intervention (subjects are unlikely to be embarrassed); prospective **agreement**; collection **of non-sensitive** information via audio recording; **concealment with notice**. **Limited IRB review is required.*
3	Subjects are given educational materials with the intention of changing their behavior (e.g., smoking cessation), and then they report sensitive health history via an anonymous survey. The investigator describes the study procedures and intervention, and subjects prospectively agree to participate.	Yes	**Benign** behavioral intervention (not likely to pose a significant lasting adverse impact); prospective **agreement**; survey collects sensitive data **anonymously**.
3	Teams of adult volunteers prospectively agree to engage in brief cooperative activities and then verbally report their progress.	Yes	**Benign** behavioral intervention (brief); prospective **agreement**; collection of **non-sensitive** information through **verbal** responses.
3	Subjects prospectively agree to play an economic game and complete a written survey about negative attitudes toward their employer. The survey includes dates and employment history that could be used to re- identify respondents.	Yes*	**Benign** behavioral intervention (harmless); prospective **agreement**; collection of **sensitive** (potential employability risk) **identifiable** information via written **responses**. **Limited IRB review is required.*

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Exempt category	Study example	Exempt?	Explanation
3	Subjects prospectively agree to give an impromptu speech and complete a math task aloud while being rushed. Deception is involved in the form of frowning judges. Subjects are not told they will be unaware or misled regarding the nature or purpose of the study.	No	The behavioral intervention is **not benign** (subjects could be embarrassed; without debriefing, the intervention could pose a significant lasting adverse impact). The use of **deception without notice** is not allowed.
3	Investigators videotape pedestrian behavior when a "Walk/Don't Walk" sign is manipulated for research purposes.	No	Exempt category 3 does not apply to studies where subjects are **not aware** that they are participating in research.
3	Benign behavioral intervention followed by verbal responses from children.	No	Exempt category 3 is limited to research with **adults**.
3	Subjects undergo electroencephalogram (EEG) while presented with visual stimuli on a computer screen.	No	**Medical** interventions (medical tests, procedures, and/or use of devices) are not behavioral interventions.
3	Study collects data via activity trackers (e.g., Fitbit) and eye trackers.	No	Data may not be collected via **physical** procedures.
3	Internet survey with embedded intervention (health scenarios) links responses to respondents' criminal records.	No	**Linking** data with other personally identifiable information is not permitted under exempt category 3.

This tip sheet has been adapted from materials developed by the University of Michigan Health Sciences & Behavioral Sciences IRB.